REMARKS

Claims 1, 9, and 19 were pending. The Examiner rejected claims 1 and 19 and objected to the Specification for informalities related to section headings. Applicants have herein amended the Specification to include section headings. No new matter has been added.

Applicants request the Examiner to clarify the status of claim 19 in the next Office Action. Claim 19 was newly presented with the Request for Continued Examination filed September 11, 2008. In the present Office Action, the Examiner acknowledged the entrance of the R.C.E. Clarification of the status of claim 19 is requested.

In light of the amendments and the remarks herein, Applicants respectfully request reconsideration and allowance of claims 1, 9, and 19.

Withdrawal of Previous Rejections

Applicants thank the Examiner for the withdrawal of the rejections under 35 U.S.C. § 103(a) over WO 01/25242, U.S. Pat. 6,790,850, and U.S. Ser. No. 10/863995.

Applicants thank the Examiner for the withdrawal of the obviousness-type double-patenting rejections over claims 1-11 of U.S. Pat. 6,790,850 and claims 20-26 of U.S. Ser. No.10/863995.

Obviousness Type Double Patenting Rejections

Claims 1 and 9 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of co-pending U.S. Ser. No. 10/528270.

Applicants disagree for the reasons of record. Applicants respectfully assert that the Examiner has not made out a *prima facie* case of obviousness using the principles clearly set forth by the Federal Circuit in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1363 (Fed. Cir. 2007), and *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, 2008 WL 2791884 (Fed. Cir. July 2008). In those cases, the Federal Circuit makes clear that in order to assert that a compound is obvious over a compound in the prior art, one must: 1) identify a

starting reference point or points in the art (i.e., a lead compound), prior to the time of invention, from which a skilled artisan might identify a problem and pursue a potential solution; 2) identify some reason, available within the knowledge of one of skill in the art, to make the specific molecular modifications necessary to result in the claimed compound; and 3) identify " some reasons for narrowing the prior art universe to a finite number of identified, predictable solutions." In *Eisai* the Federal Circuit stated "[i]n other words, post-KSR, a *prima facie* case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound."

The Examiner asserts that the Berge reference supports a "sodium salt" as a lead compound. Applicants reiterate their comments on the teachings of the Berge reference and respectfully assert that identifying a particular salt *counter-ion* to be used is not sufficient to identify "a lead compound", *i.e.*, the compound itself. Moreover, the Examiner refers to the M.P.E.P. (2144.08) to support the proposition that any stereoisomer would render any other stereoisomer obvious, yet, given the holding in *Eisai* and *Takeda*, such a finding *presupposes* the identification of at least one stereoisomer or compound as a lead compound to modify. The Examiner has failed to identify why one of ordinary skill would start with the particular stereoisomer compound in the cited case as a lead compound and modify it to result in the claimed monosodium salt compound of the present case, particularly given the *other* choices of structurally related compounds as possible lead compounds in other references, including WO 01/25242 (U.S. Pat. 6,790,850). Surely the Examiner cannot be asserting that every position isomer, stereoisomer, homolog, and salt form of every compound in the art is *prima facie* obvious merely because the prior art compound was synthesized. Demonstration of the mere synthesis of a compound cannot support the Federal Circuit's mandate to "identify a lead compound."

Even if the Examiner had made out a *prima facie* case, the Declarations provided in the present case and in U.S. Ser. No. 10/528270 are more than sufficient to rebut the *prima facie* case. The Examiner has asserted, relying on the M.P.E.P., that structurally similar compounds are presumed to have similar properties. Yet the Bonnert declaration previously submitted in the

present case demonstrates that another structurally similar compound in the WO 01/25242 (U.S. Pat. 6,790,850) case does *not* demonstrate similar properties as the claimed monosodium salt compound whether it is *either* the non-salt or the monosodium salt form (*see* paragraphs 12 and 15 of the Bonnert Declaration discussing Example 7 of WO 01/25242). Clearly the "presumption" that structurally related compounds and sodium salt forms will behave similarly has been rebutted here. Moreover, the Bonnert Declaration also demonstrates that the *non-salt* version of the claimed monosodium salt compound (*see* paragraphs 13 and 14) was not an acceptable drug candidate. If going from a monosodium salt form to a non-salt form *of the same compound* yields unpredictable results, Applicants cannot understand why the Examiner would continue to assert that the cited art compound, which is a *different* compound, would continue to be presumed to behave similarly with respect to the claimed compound.

In order to further prosecution, however, the Applicants herein file a Terminal Disclaimer with respect to U.S. Ser. No. 10/528270. Withdrawal of the double patenting rejections is requested.

CONCLUSION

Applicants respectfully assert that all claims are in condition for allowance, which action is hereby requested. The Examiner is invited to telephone the undersigned attorney if such would expedite prosecution.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 2/11/09

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